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# **Incremental innovation – a generic industry perspective**

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## Overview of presentation

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1. Introduction

2. Freedom to operate analysis – a burden?

3. Effectiveness of mechanisms for revoking “secondary” or “follow-on” patents

- Litigation
- Opposition proceedings

5. Method of use patents – a particular problem?

6. Conclusions

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## Introduction

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*Some general points on evergreening*

This is not a simple innovator vs. generic debate (“*Us*” and “*Them*”).

The generic industry depends on the innovative pharmaceutical industry for a continuous flow of new products that have been put through extensive clinical trials in human subjects.

It is vital for both sides of the industry that the innovators continue to be successful at what they do.

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## Introduction

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### *Some general points on evergreening*

During the lifecycle of a small molecule product, improvements are likely to be discovered. It is unrealistic to expect innovator companies to keep on producing exactly the same product according to its original formulation, when experiences both in the laboratory and in the clinic may demonstrate that a particular finished dose product (and perhaps the efficiency of its manufacture) can be improved.

Incremental innovation in the pharmaceutical industry is therefore inherent and overall it is probably a public good that is to be encouraged!

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## Introduction

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### *Some general points on evergreening*

This does not necessarily mean that all incremental innovation warrants a 20 year term of patent protection.

A balance has been struck in the patent law in Europe and the USA, which requires an innovation to be both new and to meet a certain level of inventiveness in order to qualify for patent protection. Because these are legal standards assessed by judges on a case-by-case basis, it is a fact of life that they can appear to vary with judicial trends.

Broadly, the balance in these countries is “about right” at the present time.

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## Introduction

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### *Some general points on evergreening*

However, there have historically been deficiencies in the patent systems both in Europe and in the USA for curing administrative decisions to grant monopoly rights for undeserving incremental innovations.

There have been attempts on both sides of the Atlantic to address these problems (e.g. post-grant oppositions in the USA, the Unified Patent Court in Europe). However, it should be borne in mind that these are efforts directed at improving the *efficiency* of the grant (and revocation) of patent rights.

This may be where most effort should be focused – rather than striving to re-write the fundamental rules of what should “qualify” for patent protection.

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## How do generic companies deal with extensive patent landscapes protecting incremental innovations?

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### *Freedom to operate (FTO) analysis*

This is well-established as a necessary step to be carried out in advance of a generic product launch in our industry.

It is an analysis directed at avoiding or reducing patent infringement risk. The purpose is to identify the risks posed by patents held by third parties, in particular innovator companies (but also generic industry competitors).

The aim is to determine the best way to launch a product on to the market, if possible, in a risk-free way – that avoids third party patents.

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## What is a freedom to operate analysis?

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It is not “rocket science”. Essentially, it is a three step process:

1. Do a search for relevant patents.
  2. Evaluate the risks revealed by the search.
  3. Consider solutions in order to mitigate any risks that might be revealed after evaluating the search results.
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## What is a freedom to operate analysis?

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A FTO analysis involves a search for all patents:

- *basic chemistry (“composition of matter”) patents*
- *supplementary protection certificates / patent extensions*
- *formulation patents*
- *physical form (crystals/polymorphs) patents*
- *method of treatment or ‘use’ patents...*

It is important to have a very clear understanding of how patent claims are interpreted in different countries and how variations in the legal approach to claim construction and infringement can affect the FTO analysis.

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## What happens if a “block” is revealed?

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If a ‘patent block’ is revealed by a FTO search, the strength of that block can be evaluated.

This may require a more detailed level of experience and insight, that may not always be available in some of the smaller generic companies. However, there are well-known procedural options available to deal with a “block”, if the time, effort and expense can be justified.

*In Europe, we currently have the opposition procedure at the EPO (provided that the opposition is filed within 9 months of grant) and the option of national revocation proceedings in the individual countries.*

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## **Oppositions in the European Patent Office – some thoughts**

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- Very slow (especially once appeal process has been taken into account)
  - Document-based process, therefore difficult to have expert evidence properly considered as to the true state of the art, according to the skilled person
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## National patent litigation in Europe – some thoughts

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- Multi-jurisdictional litigation can be expensive
  - Need to have a good knowledge of national litigation idiosyncrasies
  - Inconsistency of decision-making by the national courts can be frustrating
  - Needs very efficient project management skills, to coordinate the timing of the outcome of the case and the date of any regulatory approval / product launch
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## Method of use patents in Europe – a particular problem?

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### Legal background

“Method of use” claims purporting to protect a novel and inventive use of an otherwise old drug are available in Europe. Previously, the claim was required to be in the form: *“the use of compound X in the manufacture of a medicament for the treatment of disease Y”*

- hence the terminology “Swiss” claim or “Swiss-type” claim.

Now, Article 54(5) EPC 2000 ensures that such “use” claims in European patent applications need not be in “Swiss” form

(with effect from 28 January 2011, the EPO has no longer been accepting claims in “Swiss” form).

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## **Method of use patents in Europe – a particular problem?**

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It is necessary for manufacturers of generic medicines to provide detailed printed instructions on the intended use and dosage of their products.

This can give rise to infringement claims (direct/secondary infringement), based on what is said on the generic drug product's label (or leaflet) about the intended use of the product.

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## Method of use patents in Europe – a particular problem?

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There is a “regulatory fix” for generics in the EU:

Directive 2001/83/EC (as amended) – Article 11

*For authorisations under Article 10, those parts of the summary of product characteristics (SmPC) of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed **need not be included**.*

Deleting (“skinny labelling” or “carving out” the patented indication) from the label is therefore an option for generic companies.

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## Method of use patents in Europe – a particular problem?

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This “regulatory fix” does not give generic companies immunity from patent infringement.

What if doctors ignore what is on the label and still prescribe the generic product for the patented use? Does this give rise to patent infringement?

*Raises difficult policy issues at the interface of patents and public health.*

Ongoing case in the English Patents Court: *Warner-Lambert v Actavis*.

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**Questions?**

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